



Generic Medication and Management Issues: A Narrative Review of the History, Inhibitors, and Impact on the Competitiveness of the U.S. Pharmaceutical Market

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Abstract:

Objective: Describe landmark events and legislation impacting the generic pharmaceutical market; depict the landscape of generics, influenced by varying inhibitors; and portray the utility of generics and potential. Management issues are present in the topic of Generic Medication.

Methods: Utilizing research databases of PubMed, JSTOR, and CINAHL, a multitude of peer-reviewed journal articles were analyzed to gain a full understanding of the generic pharmaceutical market and its inhibitors. Criterion for inclusion in this narrative review included: the article must be peer-reviewed and be published within the past twenty years and contain qualitative and quantitative data.

Results: It was found that inhibitors to the success of generics include supply chain inefficiencies, low profit margins, strategic patenting, price dispersion, and perception biases, all of which need to be further researched. Further, legislation has great influence on the generic market, and there is ample room for future legislation to improve generic accessibility and availability.

Conclusion: There are various policy implications, supply chain predicaments, and biases that impact the accessibility and availability of generics. The review describes how perception can impact preference for generics, how it has evolved and provides management advice for providers. The offered solutions include improvements in legislation aimed at price reduction generic accessibility, and education surrounding pharmaceutical health literacy. The call for research is to study aspects that affect generic drug shortages, inflict abnormal market behavior, and study the future implications of legislation on the generic market.

Keywords: Generic medications, pharmaceutical industry, supply chain, perception biases, legislation, bioequivalence, drug shortages.

1. INTRODUCTION

The introduction of generic medications has significantly altered the landscape of the U.S pharmaceutical market. These drugs, which are bioequivalent to their brand-name counterparts but are sold at a fraction of the price, have been pivotal in making healthcare more affordable but the prevailing systemic issue presented by pharmaceuticals is no new aspect of modern medicine. Instead, the pharmaceutical industry continues to increase in complexity and the scope of stakeholders is increasing as well. There exists an intersection of market and policy about pharmaceuticals, one that is a culmination fervent back and forth between the goals and aims of varying stakeholder groups. Generic medications often lie at the central connection between policy and market, this in turn gives rise to controversy for how to balance the line between market affordability, accessibility, and profitability, and policy implementation.

The concept of generic medication is not something new, it can be traced back to the early 20th century. It was not until the passage of the Drug Price Competition and Patent Term Restoration Act of 1984 which is commonly known as the Hatch-Waxman Act, that generics gained traction in the U.S. This legislation aimed to foster a balance by encouraging pharmaceuticals and expediting the

availability of more cost-effective drugs by allowing generic manufacturers to use the data of the original brand name drugs and rely on their safety and efficacy thus creating a simplified and accelerated approval process [1].

The inflated costs of pharmaceuticals prevalent in the United States account for fourteen percent of total healthcare spending and about ninety percent of all prescribed medications are the generic brands but, medications that do not have generic alternatives make up a greater portion of those expenses [2]. For branded medications without a generic alternative, the pricing can go unchecked leaving many consumers vulnerable to the monopolistic market. For example, the price of one branded medication experienced a price increase of fifty-five times greater than its original price, unchecked by a market that could offer no alternatives [2]. Generic brands help to reduce costs and balance the market, yet there is often great pushback from originator drug manufacturers that look to keep a strong foothold in the market.

The first mention of a policy intervention in the medical product market for brand versus competitor products was in 1888, when the American Pharmaceutical Association published its National Formulary, this was established to help prevent counterfeit products from imposing as branded ones. The Federal Food and Drugs Act began the first pharmaceutical regulation and would later be the backbone of the powerful agency, the FDA [3]. In 1937, 107 people perished after consuming Elixir Sulfanilamide, which prompted congress to pass the Federal Food, Drug, and Cosmetic Act [3]. This was a pivotal piece of legislation designed to curb the risks of medical products by making sure that drugs were tested and proven safe before being approved for public consumption. In the 1960s, Senator Gaylord Nelson was the first individual to advocate for the concept of generic drugs and their place in policy, based on the hearings of the Senate Subcommittee on Monopoly and Antitrust [4]. This strongly contrasted with the growing efforts of the time to strengthen lobbying for brand name medications [4].

The introduction of Medicare and Medicaid brought to light the value of promoting and using generic medications– in hopes of achieving cost-effectiveness for the government programs. The Generic Drug Enforcement Act passed in 1992 did require that generic drug manufacturers produce more relevant data to prove the quality and bioequivalence of the generic product to the branded one [3].

The FDA is stringent in its approval process for generic medications and works to ensure that generics are as safe and effective as their branded predecessors. Generic drug manufacturers must file an Abbreviated New Drug Application (ANDA), which essentially designates that the generic manufacturer does not have to include animal or human clinical trial data for the medication– as it is already done for the branded drug– but, that the manufacturer must still provide data to show that the medication performs in the same manner that the branded drug does, thus proving its safety and efficacy [5, 6].

The generic brand must also enter the bloodstream in the same amount of time and deliver the same amount of active medication as the branded drug as well– which is an important market of bioequivalency [5]. The basis for this equivalence is in pharmacokinetics such as that the drug must have the same amount of active ingredients, the same strength and route of admission, and be bioequivalent with the same purity and quality as the original branded drug [6]. The FDA publishes the “Orange Book” which is the “Approved Drug Products with Therapeutic Equivalence Evaluations” that describes which generic products are approved and their reference drugs, keeping track of the safe and efficacious generics and providing a stamp of FDA approval [6]. One study found that in a 12-year study of generic performance compared to their innovator drug performance, the generic drugs performed similarly with statistical significance, citing that the FDA’s approval process is valid and produces products with similar efficacy and effectiveness [7].

2. METHODS

The authors, for this narrative summary, used various databases of scientific, peer-reviewed literature including PubMed, the National Institute of Health, CINAHL, JSTOR, and articles published by the FDA. By using keywords such as: authorized generics, historical analysis, patenting, drug shortages, supply chain inhibitors, bioequivalence, ANDAs, efficacy, and more in our advanced searches. We reviewed a compilation of twenty journal articles aimed at understanding the implications and current

positioning of generics in the United States marketplace. These articles include both qualitative and quantitative data that allowed for greater insight into the broad and niche topics surrounding our analysis, allowing us to compile an overview of the current place of generics in the pharmaceutical industry.

3. RESULTS

A study by Teasdale et al. [8] found that pricing variations in generic prescription medications in the U.S are primarily focused on the fact that even though the costs in the pharmaceutical supply are less in the U.S, the measure of generic drugs prices and price variations are still logged in at the bigger figure, which contradicted the expectations of a competitive market [8]. The conclusion is that the attempts to get around the “pharmacy benefit model” for generic medications will lead to clients getting enormous savings. This makes it clear that besides the conventional policies, an innovative approach must be used in tackling the problem of price increases and affording prescription drugs in the market.

According to research conducted by Segal et al. [9], on the aspect of pharmacy selection effects, it is essential to create enabling regulations to increase the use of safe, valid, and affordable generic medications in the United States. It emphasizes that mail-order pharmacies, which usually are viewed as an obligation by the pharmacy benefits managers, can reduce the use of generic medications within diverse groups. The result shows that more regulatory attention might be given to these pharmacies if their practices reduce the accessibility of generic drugs for patients. Tucker and Daskin [10] stress that improving pharmaceutical supply chain reliability is the most essential factor for reducing drug shortages, especially in the context of COVID-19.

The FDA assures that generics can be used for almost perfect substitutes of name-brand drugs. Shortage causes have been identified as greater concentration of generic providers, supply chain lengthening, and increased FDA scrutiny in production centers. Pressures to lower prices have led to lower investment in production capacity [11]. According to Oorschot et al, “there are no root causes of drug shortages in normal situations. Instead, a web of interconnected causal relationships underpins drug shortages, meaning that root causes are not merely difficult to find, but nonexistent. This is an important finding, especially considering efforts by supply chain actors and policymakers to find root causes of drug shortages, and a tendency toward quick fixes. Instead of focusing on “fishbone analyses” (i.e., linear cause-and-effect relationships) to find root causes, decision-makers should be focusing on “fishing net analyses,” which allow them to connect linear relationships in a systems view of the problem. This would require close collaboration between key stakeholders. Although this view is less likely to offer decision-makers a single “right” answer, it will certainly yield an alternative, more useful framing of the problem” [12].

Based on the aspect of medication effects, Desai et al. [13] concludes that there is no significant difference between generic and brand name drugs on the American market according to the study on medicine-related claims collected from an existing US health insurance database. Research indicates that generic prescriptions are as operative as branded ones in providing patients with similar clinical results. These results could be used to improve educational interventions that seek to enhance the patients' and providers' confidence in the effectiveness of generic drugs for the control of chronic diseases.

Concerning oral and injectables of generic prescription in the U.S., Pilon et al. [14] compare the medication trends, healthcare resources use, and expenditure in Medicaid recipients who started “second-generation long-acting injectable agents” and atypical generics orally in the United States. The study showed that patients on Medicaid who were switched to Long-Acting Injectables instead of oral drugs, had less healthcare utilization and less total healthcare spending [14]. The long-acting injections were associated with a reduced hospitalization, emergency department visits, and outpatient visits, which led to cost savings, improved outcomes, and patient actualization. The outcomes of this investigation thereby suggest that long acting injectables may be of value for Medicaid beneficiaries struggling with mental disorders in terms of reducing healthcare usage and costs.

Generic prescription circulation and usage in the U.S. have all these multiple factors ranging from being labeled with different prices, selecting a pharmacy, damaged supply chain, medicines

classification, and the choice of oral tablets over injections. Management of these elements on the to-do list is crucial if the aim is to ensure the availability of quality generic drugs at an affordable price and good patient outcomes, which is the end target of healthcare facilities.

One aspect to consider is the impact of personal preferences regarding generic drugs. Both patients and physicians create their own perceptions about generic medications, and the two often work in tandem and affect each other based on the authoritative and reliant relationship present between a provider and their patient. In a sample of 509 physicians using a 5-point Likert scale, it was reported that an astonishing twenty-three percent of physicians expressed a negative perception towards the efficacy of generic prescriptions, and a further fifty percent held a negative view about the quality of generic pharmaceuticals in general [15]. On the receiving end of healthcare, patients cited that providers should prescribe a generic when it is available (eighty-three percent of 753 surveyed) but over one-third of the same group surveyed reported that they would rather be prescribed a brand-name drug, and a total of forty-six percent requested a brand name prescription rather than a generic [16]. However, most patients (ninety-seven percent) report that they trust a generic's efficacy and quality if prescribed by their provider, which illustrates a strong correlation between physician preference and consumer trust [16].

These preferences are based on personal ideas that large stakeholder groups in the healthcare industry have toward generic substitution. While the vast majority believe that generics are less expensive, a study found that about sixty percent of patients believe that generics provide a greater value, but less than forty-six percent decide to take generic prescriptions when a branded alternative is available [17]. In this same study, it was discovered that almost one-fourth of patients believed branded medications are more effective than generics [17]. Patients are not the only stakeholder group to perceive generics as lower quality, or less efficacious. In a literature review of fifty-two articles focused on the perceived bias prevalent amongst major stakeholder groups— an astounding twenty-eight percent of providers and twenty-three percent of pharmacists believe generics to be less effective than their branded biosimilar [18]. Furthermore, one-third of pharmacists were likely to believe that generic medications offer inferior quality, and one-fourth of physicians believed that the generics caused more side effects [18]. The important note to consider here is that the data reported for these assumptions are based on personal biases and subjective beliefs- not objective clinical data or cited outcomes.

There are many factors driving these perceptions. Segal et. Al [19] found that individuals that presented a lower health literacy, and those who belonged to lower income brackets were more likely to hold negative views about generic drugs. The class of drug that a generic belongs to also has an impact on whether it is viewed positively or negatively and chosen rather than the branded one [19]. For patients that partake in polypharmacy (described as being regularly prescribed in between five to ten medication), a cross-sectional study of one hundred and thirty of these patients found a positive association between the personal importance of the drug to the individual, and their adherence to their medication regimen [20]. The patient's personal importance attached to their medication, and thus their adherence, is affected by whether it is branded or generic [20]. However, patients are not the only ones who share concerned feelings. Physicians that are older in age are more likely to not prefer generics, and less likely to recommend them to their patients. Physicians are more likely to express safety concerns about generics compared to pharmacists or patients [15, 18]. This impacts the ability of consumers to access the generics greatly, and impacts their perception as well, since a provider is deemed the imminent authority on medication access and opinion for most patients. However, when patients choose generics, the results appear favorable and contrast with their initial perceptions. Out of 5,542 patients who switched from a branded medication to a generic one, less than five percent switched back to the branded drug [20].

4. DISCUSSION

Most would concur that generic prescriptions are more cost effective and are valuable to institutions such as Medicare and Medicaid, as well as individual stakeholders in the industry such as providers and patients. However, since the inception of regulation in pharmaceuticals and competitive interests in both the policy arena and the market, debate has ensued as to whether generics live up to the value they represent and if they are truly as effectual as their branded predecessors. In the face of growing healthcare costs, pharmaceuticals play a big role, and thus a call for strategic price reductions for drugs is the embodiment of many individuals' pleas. Generics are the most straightforward answer to this predicament; however, they are not currently an effective, singular solution.

This is due to a multitude of factors, namely centered around the intersection of policy and market. It was found that generics often contradict typical market behavior, due to price dispersion and variation that leads to inequitable market outcomes [8]. The pharmacy benefit model (PBMs) contributes to this atypical behavior, as the third-party player presents a relationship that bottlenecks the patient's ability to obtain pharmaceuticals and increases prices. Further contributing to this atypical market conundrum are the supply chain issues plaguing the pharmaceutical industry. COVID-19 gripped every aspect of the medical realm, and pharmaceuticals were no exception. A multitude of drug shortages, combined with decreased labor forces incited an inequitable relationship between supply and demand, which leaves consumers without the ability to obtain needed medications. Exacerbating this issue is the patenting cycle for pioneer drugs and subsequent generics. If pioneer drug patents are granted secondary patents based on minute changes that are not impactful to the efficacy of the drug, or if the patent filer attempts to participate in ever-greening practices, generics are unable to reach the market and thus supply is inhibited—contributing to an insatiable demand and unchecked pricing. For drugs that do not currently have generic alternatives, the profitability index is greater for pharmaceutical companies. For generic manufacturers, the profitability margin is much lower, which decreases the demand for generic innovation and increased market presence—putting the pharmaceutical market in a standstill.

The management of generic medications is an area that involves pharmacies, manufacturers and the perception of the public, and how or if that can be managed by providers and the ever-increasing knowledge of the overall general public. One study showed a concern for strategies designed to achieve a flat-rate benchmark for generic utilizations, which would impact payments, and possibly reduce or increase the use of generics, depending on the payment [21]. It is also important for pharmacies and providers to know the perception of consumers regarding generic medications. Consumers' confidence has increased over the past four decades or more in generics, but not for all medications and an awareness by providers and pharmacies is a must in these cases [22]. The majority of consumers now do understand the major cost in health expenditures that generics provide [22]. Thus, the management of generic medication requires a knowledge of consumer perception and good communication with the patient, to ensure they will accept the generic equivalent of a brand-name medication. Management decisions such as inventory to pharmacies, and providers recommending generics are all a result of this narrative summary.

The market is not the only factor contributing to the current state of generic consumption and availability in the United States. Perception and preference present a great impediment to furthering the popularity and advocacy for generics. Repeatedly, patients are knowledgeable about the economic value that generics pose but are often unwilling to prefer or consume the products themselves. Providers and pharmacists are surprisingly wary of generics and often hold a negative perspective regarding their quality and effectiveness. Since generics are required to be chemically and efficaciously similar to branded medications, these perspectives are not congruent with the results and outcomes found clinically about generics. The history of generics offers insight into the stringent and proven methods and standards that the FDA holds for generic medications and lends a torchlight to the darkness of biased perception. It is concerning that many patients and providers hold negative perceptions about generics, but these are improving as greater evidence is being cited and market exclusivity is ending for many highly coveted drugs, allowing for greater market room for generic products [16]. Patients even have varying perceptions towards generics based on whether or not the drug is injectable or administered orally as well as the class of drug in which the generic falls. This can be attributed to the individual patient's concerns and the patient's personal importance or attachment to the drug in question.

The call for improved pharmaceutical legislation has echoed continually since the 1960s, and the most recent legislation regarding Medicare's ability to negotiate pharmaceutical pricing is indicative that this trend will only continue. Policies aimed towards improving generic access and increasing market space for generic manufacturing are necessary to improve upon the supply chain inefficiencies and the ever-greening practices of long-term patents. Policies surrounding the patenting practices of pioneer drugs and generics are a critical area of interest that will surface as the government's intervention in drug negotiation increases. Education plays a significant role in generic access as well, and providers and patients alike should be informed on the safety and efficacy of generics to negate the negative

perceptions that tend to follow these drugs. A lack of health literacy is culpable for these negative perceptions as well, as can be curbed by improving physician's perceptions towards generic medications and cultivating their prescribing practices towards the products that will result in savings for their patients. Management practices aimed at improving the prescribing practices within institutions and individual practices can make a vast difference in physician behaviors and result in cost savings for patients, and improved patient trust in both physician relationship and generic efficacy. Educating patients on the efficacy and value that generics have is a vital step in improving perception and reducing unnecessary biases towards generic products.

Regarding future research, there is much left to be understood about the correlation between the psychological preferences of patients and providers and the impact that this has on provider suggestion and patient choice. While this review found that there is certainly an association between the two, there is room to improve upon understanding the multifactorial aspects that infringe upon choosing generics and that inhibit trust in them. An analysis of the abnormal market behavior of generics and the price dispersion that occurs for different drug classes would be valuable to understanding how to market generics and improve consumer adoption. Research can be built upon understanding the nocebo effect regarding generic pharmaceuticals, and what factors affect them. Finally, a future area of research would be to longitudinally study the impacts that the Medicare prescription negotiations will have on Medicare spending, population health outcomes, and generic market improvement.

5. CONCLUSION

This narrative review of existing literature adds to a body of study aimed at improving knowledge surrounding the pharmaceutical industry and improving understanding of the value and efficacy of generic medications. This review offers insight into the important policy implications that affect generic medication manufacturing both positively and negatively. Our review finds that generics are often perceived as lower in quality and efficacy by a variety of stakeholders in the medical realm: providers, pharmacists, and patients. These perceptions are the culmination of a variety of factors such as socioeconomic status, health literacy, and even provider bias. However, more research needs to be conducted to understand the full effects that these factors may have, to discover more factors, and to begin to understand how to combat them. Our review also finds that supply chain issues and price dispersion are contributing to drug shortages of generic medications, and there is great room for improvement. The evergreening patent cycle for pioneer drugs can inhibit the introduction and success of generics in the pharmaceutical market. While it was found that many patients view generics as obtaining a high economic value, the distrust still prevalent amongst usage cites a need for improved health literacy education, provider preference and utilization, and improved policies aimed towards improving generic accessibility, manufacturing, and market share.

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